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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,640	03/21/2001	Kiichiro Yano	10287-071001/MGH 1585.1	2899

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EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/813,640

Applicant(s)

YANO ET AL.

Examiner

J. Eric Angell

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are pending in the application.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, 11 and 12, drawn to a method for increasing hair growth/thickness in a subject by administering VEGF polypeptide, classified in class 514, subclass 2, for example.
 - II. Claims 1, 3, 4, 6, 11, 13, 14, 16, drawn to a method for increasing hair growth/thickness in a subject by administering a polypeptide which increases the level of VEGF protein, classified in class 514, subclass 2.
 - III. Claims 1, 3, 5, 6, 11, 13, 15, 16, drawn to a method for increasing hair growth/thickness in a subject by administering a transition metal which increases the level of VEGF protein, classified in class 424, subclass 9.2.
 - IV. Claim 1, 7-11 and 17-20, drawn to a method for increasing hair growth/thickness in a subject by administering a nucleic acid encoding VEGF protein, classified in class 514, subclass 44.
 - V. Claims 21-23 and 25, drawn to a method of inhibiting hair growth/thickness by administering a polypeptide, classified in class 514, subclass 2.
 - VI. Claims 21, 22, 24 and 25, drawn to a method of inhibiting hair growth/thickness by administering a nucleotide which decreases VEGF expression, classified in class 514, subclass 44.

- VII. Claims 21, 22 and 26, drawn to a method of inhibiting hair growth/thickness by administering an anti-VEGF antibody, classified in class 424, subclass 130.1.
- VIII. Claims 27 and 28, drawn to a method for evaluating whether a subject is at risk for hair loss by detecting misexpression of VEGF, classified in class 435, subclass 6.
- IX. Claims 29-31, drawn to a method of selecting a compound which regulates hair growth/thickness, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, although inventions I-IV are all methods of increasing hair growth/thickness, these inventions are unrelated because they encompass the administration of therapeutic compounds which are chemically, structurally and patentably distinct. For instance, Group I encompasses the administration of VEGF protein, Group II encompasses the administration of a polypeptide which increases the level of VEGF protein, Group III encompasses the administration of a transition metal, and Group IV encompasses the administration of a nucleic acid encoding VEGF protein. VEGF protein, a polypeptide which increases the level of VEGF protein, a transition metal, and a nucleic acid encoding VEGF protein are all chemically, structurally and patentably distinct. Proteins/polypeptides function by having various cellular functions such as structural and enzymatic functions. Transition metals are chemical elements which can function as co-factors or activators of biologically active

Art Unit: 1635

compounds. Nucleic acids also have various functions such as encoding proteins, templates for PCR reactions, or as probes in hybridization assays. Therefore, Inventions I-IV are unrelated.

3. Inventions V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, although inventions V-VII are all methods of decreasing hair growth/thickness, these inventions are unrelated because they encompass the administration of therapeutic compounds which are chemically, structurally and patentably distinct. For instance, Group V encompasses the administration of a polypeptide, Group VI encompasses the administration of a nucleotide, and Group VII encompasses the administration of an anti-VEGF antibody. Polypeptides, nucleotides and antibodies are all chemically, structurally and patentably distinct. Polypeptides function by having various cellular functions such as structural and enzymatic functions. Nucleic acids have various functions such as encoding proteins, templates for PCR reactions, or as probes in hybridization assays. Antibodies are specialized polypeptides which interact with specific molecules and are critical elements of the immune response. Therefore, Inventions V-VII are unrelated.

4. Inventions I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the inventions have different modes of operation, different functions and different functions. Inventions I-IV are unrelated, as are Inventions V-VII, for the reasons mentioned above. Additionally Inventions I-IX are unrelated because the inventions are

Art Unit: 1635

drawn to methods having different functions and effects. For instance, Inventions I-IV are drawn to methods of increasing hair growth/thickness, Inventions V-VII are drawn to method of decreasing hair growth/thickness, Invention VIII is drawn to a method to evaluate the risk for hair loss, and Invention IX is drawn to screening method to identify regulators of hair growth.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the search required for each Group is not coextensive with the searches required for the other Groups (e.g., the searches require different search strategies, different search terms and searches of different classifications), restriction for examination purposes as indicated is proper.

7. A telephone call was made to Samantha Bell on September 28, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1635

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
September 28, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER